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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/181,027	10/27/98	HAAF T	A-65680-4/RF

HM12/0425

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EXAMINER	
BRUSCA, J	
ART UNIT	**PAPER NUMBER**
1631	10

DATE MAILED: 04/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/181,027	Haaf et al.
Examiner	**Group Art Unit**
John S. Brusca	1631

☒ Responsive to communication(s) filed on *3/27/00*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *40-55* is/are pending in the application.

Of the above, claim(s) *45* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *40-44 and 46-55* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The group and or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631.

2. This rejection is a non-final rejection due to the new grounds of rejection not necessitated by Applicant's amendment. In the Office Action mailed 9/21/99 the rejections over Scully et al. and Sharan et al. were incorrectly cited under 35 U.S.C. 102(b) rather than 35 U.S.C. 102(a). Scully et al. was mischaracterized as teaching BRCA2 instead of BRCA1. The granted priority date was the instant filing date instead of the filing date of parent Application No. 09/007020.

Claim Objections

3. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 46-54 have been renumbered 47-55. The dependencies of renumbered claims 47-55 have been appropriately corrected. This Office Action refers to the renumbered claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 47-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to human cells comprising two recombinant nucleic acids, one comprising a Rad51 gene, and the second comprising a tumor suppressor gene. The specification does not disclose human cells comprising the two claimed recombinant nucleic acids, nor does it disclose a method of using such cells. The instant specification discloses methods of using the claimed combination of nucleic acids for producing encoded proteins for use in binding assays on page 23 and for generating specific antisera for in situ staining on page 31. The specification discussed on pages 26-27 combinations of Rad51 and tumor suppressor genes for the purpose of expressing the genes individually so that the expressed proteins may be isolated and purified. The Rad51 and tumor suppressor proteins must be individually purified for use in binding assays and to generate antisera.

Claim Rejections - 35 USC § 102

6. For the purposes of prior art, the instant application is granted an effective filing date of 1/14/98 because the instant specification discloses methods of using the claimed combination of nucleic acids for producing encoded proteins for use in binding assays on page 23 and for generating specific antisera for in situ staining on page 31. Claimed Provisional Applications 60/035834 and 60/045668 do not disclose methods of using the claimed combinations of nucleic acids for binding assays or for generating combinations of antibodies specific for the encoded proteins.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 40 and 43 are rejected under 35 U.S.C. 102(a) as being anticipated by Sharan et al. (Reference 3 in the Form PTO 1449 received 4/15/99).

The claims are drawn to compositions comprising nucleic acids encoding Rad 5, and BRCA2 in a physiological carrier.

Sharan et al. show in the methods section on pages 809-810 the use of genes encoding Rad51 and BRCA2 to construct two-hybrid assay vectors to measure binding between Rad51 and

BRCA2 proteins. The two-hybrid assay is done in a cell, and therefore shows a physiological carrier. Sharan et al. show such binding assays in figure 5.

Therefore, Sharan et al. anticipates the claimed invention.

9. Claims 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Sturzbecher et al. (Reference 2 in the Form PTO 1449 received 4/15/99).

The claims are drawn to compositions comprising nucleic acids encoding Rad 51 and p53 in a physiological carrier.

Sturzbecher et al. show in the materials and methods section on page 2000 a gene encoding Rad51, and its use for in vitro transcription/translation. Sturzbecher et al. show in the materials and methods section on page 2000 a gene encoding p53 and its use to express in E. coli cells p53 protein. Sturzbecher et al. shows in figure 1 a binding assay between p53 and Rad51 proteins. Sturzbecher et al. shows in figure 2 analysis of cells comprising both p53 and Rad51 genes, and therefore shows a physiological carrier.

Therefore, Sturzbecher et al. anticipates the claimed invention.

10. Claims 40 and 42 are rejected under 35 U.S.C. 102(a) as being anticipated by Scully et al.

The claims are drawn to compositions comprising nucleic acids encoding Rad 51 and BRCA1 in a physiological carrier.

Scully et al. shows in the Experimental Procedures section on page 273 genes encoding p53 and BRCA1 proteins. Scully et al. shows on page 267 and figure 3 the use of genes encoding p53 and BRCA1 to transiently transfect cells followed by immunoprecipitation to demonstrate

binding between p53 and BRCA1. Scully et al. shows in figure 3 analysis of cells comprising BRCA1 and Rad51 genes, and therefore shows a physiological carrier.

Therefore, Scully et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sturzbecher et al. in view of Scully et al. in view of Sharan et al.

The claims are drawn to compositions comprising nucleic acids encoding Rad 51, BRCA1, BRCA2, and p53.

Sharan et al. show in the methods section on pages 809-810 the use of genes encoding Rad51 and BRCA2 to construct two-hybrid assay vectors to measure binding between Rad51 and BRCA2 proteins. The two-hybrid assay is done in a cell, and therefore shows a physiological carrier. Sharan et al. show such binding assays in figure 5.

Sturzbecher et al. show in the materials and methods section on page 2000 a gene encoding Rad51, and its use for in vitro transcription/translation. Sturzbecher et al. show in the materials and methods section on page 2000 a gene encoding p53 and its use to express in E. coli cells p53 protein. Sturzbecher et al. shows in figure 1 a binding assay between p53 and Rad51 proteins. Sturzbecher et al. shows in figure 2 analysis of cells comprising both p53 and Rad51 genes, and therefore shows a physiological carrier.

Scully et al. shows in the Experimental Procedures section on page 273 genes encoding p53 and BRCA1 proteins. Scully et al. shows on page 267 and figure 3 the use of genes encoding p53 and BRCA1 to transiently transfect cells followed by immunoprecipitation to demonstrate binding between p53 and BRCA1. Scully et al. shows in figure 3 analysis of cells comprising BRCA1 and Rad51 genes, and therefore shows a physiological carrier.

Sharan et al., Sturzbecher et al., and Scully et al. do not show use of genes encoding Rad51, p53, BRCA1, and BRCA2 in combination.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine genes encoding Rad51, p53, BRCA1, and BRCA2 because the combination of references show that p53, BRCA1, and BRCA2 bind Rad51, and the combination would be

useful to assay binding of Rad51 to p53, BRCA1, and BRCA2 by the methods of Sharan et al., Sturzbecher et al, and/or Scully et al.

Response to Arguments

13. Applicant's arguments filed 3/27/00 have been fully considered but they are not persuasive.

The new limitation to "physiological carrier" is taught by the cited references since they teach the recited nucleic acids in a physiological environment. The Applicants state that Sturzbecher et al. does not teach Rad51 and p53 genes together, however cells comprising both genes are analyzed by Sturzbecher et al. The Applicants state that Scully et al. does not teach Rad51 and p53 genes together, however cells comprising both genes are analyzed in Scully et al. The Applicants state that there is no motivation to use all three claimed tumor suppressor genes in combination with a Rad51 gene, but the motivation to use the genes together is maintained as obvious because the prior art teaches that Rad51 protein binds all three tumor suppressor gene products.

Conclusion

14. Certain papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The FAX number is (703) 305-7939. In such cases please call the Examiner at (703) 308-4231 at the time of transmission to expedite delivery of the fax. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16,

1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6 (d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

John S. Brusca, Ph.D.

Primary Examiner